

REMARKS

Claim and Specification Amendments

Claims 1-11, 14, 17, 24, 27, and 30-45 are currently pending. Applicants note that new claims 30-45 have been added with claim 30 being independent and newly added claims 31-45 dependent, directly or indirectly from claim 30. Applicants respectfully request that this Amendment be entered in the instant application.

Support for amendments to the claims and new claims can be found throughout the specification and claims as filed, considered as a whole, e.g., in claim 15. Applicants also note that in the 12 April 2005 Office Action, the Examiner stated that the incorporation of limitations from claims 11, 13, and/or 14 into independent claims would render such claims allowable. In the interest of expedited prosecution, Applicants have incorporated the limitations from claim 13 into the independent claims 1 and 30.

Applicants note that in the PTOL-326 form of the 12 April 2005 Office Action, the Examiner indicated that claims 24-29 were allowable. To expedite prosecution, the subject matter of claims 25 and 26 has been incorporated, in the alternative, into claim 24 and the subject matter of claims 28 and 29 has been incorporated, in the alternative, into claim 27. Thus, Applicants submit that claims 24 and 27 are in condition for allowance.

Claims 13, 15, 16, 18, 19, 20-23, 25, 26, 28, and 29 have been cancelled without prejudice to expedite prosecution. Applicants reserve all their rights to pursue patentability of the subject matter of these cancelled claims in this or any future applications.

The amendment to the Specification is to update the status of Application No. 09/692,205.

Applicants respectfully request entry of the above amendments and submit that the amendments are all fully supported by the specification and do not constitute new matter.

Furthermore, none of the amendments of the claims is made for any purpose relating to patentability, and Applicants do not intend the modification of the claims to be interpreted as affecting the scope of their claimed invention or to suggest that the claims should be given anything other than the full, open-ended interpretation to which their claim language is entitled.

Information Disclosure Statements

Applicants have received copies of Forms PTO-1449 filed with the Information Disclosure Statements filed 1/29/02 and 10/4/02 and appreciate Examiner's consideration thereof.

Claim Objections

The Examiner objected to claims 15 and 16. While Applicants maintain that as previously presented, claims 15 and 16 did further limit the subject matter of the previous claim, they have been cancelled. This objection is moot.

Claim Rejections 35 U.S.C. 102

Claims 1, 3-10, and 17 were rejected under 35 U.S.C. 102(b) as being anticipated by Madsen *et al.* (WO 98/10079). Applicants respectfully traverse this rejection.

The claimed invention is drawn a method of producing a heterologous peptide, polypeptide, or protein in a lactic acid bacterium comprising the recited steps.

Since "[a]nticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." [*Electro Med. Sys. S.A. v. Cooper Life Sciences*, 32 USPQ 2d 1017, 1019 (Fed. Cir. 1994)], Applicants respectfully submit that WO 98/10079 fails to teach all the elements of claim 1. For example, WO 98/10079 fails to teach that concentration of glucose is kept at a pre-selected concentration of at least about 0.5 g/L by controlled feeding of glucose.

For at least this reason, WO 98/10079 does not anticipate Applicants' claim 1 or claims 3-10 and 17, dependent from claim 1. This was conceded in the Office Action which indicated that claim 13 would be allowable if rewritten in independent form. Claim 1 now incorporates limitations of claim 13. Accordingly, claims 1, 3-10, and 17 are now in condition for allowance.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections 35 U.S.C. 103

Claim 2 was rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen *et al.* (WO 98/10079) in view of deVos (1999).

At the outset, Applicants submit that claim 2 is now in condition for allowance since it depends from claim 1, which is in condition for allowance, as discussed above.

Furthermore, this rejection is improper as it fails to include the independent claim. If the art does not teach or render obvious each and every limitation of the independent claim, then it can not meet or suggest each and every limitation of the dependent claims.

In addition, the Madsen *et al.* and deVos references are not combinable because there is no motivation in the cited art to modify the teachings of Madsen *et al.* with the teachings of deVos. The alleged motivation in the Office Action was based on an unsubstantiated statement of “well known properties of constitutive promoters” (Office Action, pp. 4).

The mere fact that elements from two references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of the combination [*In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)]. deVos discusses the phylogeny of promoters and gives a brief overview of expression systems used in bacterial systems. No motivation to modify the Applicants’ method of claim 1 is provided nor is there any motivation suggested by deVos to use a constitutive promoter in the method of Applicants’ claim 1.

Also, it was stated that one would have been motivated to utilize a constitutive promoter allegedly taught by deVos in Madsen *et al.*’s method “...by the well known properties of constitutive promoters, which include unregulated high levels of production of an operably linked gene of interest, as disclosed by deVos.” (*Id.*) No disclosure in deVos provides such motivation.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen *et al.* (WO 98/10079) in view of van Asseldonk *et al.* (1993).

At the outset, Applicants submit that claim 11 is now in condition for allowance since it depends from claim 1, which is in condition for allowance, as discussed above.

This rejection is improper as it fails to include the independent claim. If the art does not teach or suggest each and every limitation of the independent claim, then it can not meet or suggest each and every limitation of the dependent claims.

In addition, the Madsen *et al.* and van Asseldonk *et al.* references are not combinable because there is no motivation to modify the teachings of Madsen *et al.* with the teachings of van Asseldonk *et al.*

The mere fact that elements from two references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of the combination [*In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)]. *van Asseldonk et al.* teaches the use of the *usp45* signal peptide in a fusion protein with α -amylase to test the *dnaJ* promoter in a reporter system (pp. 1642). Therefore, no motivation to modify the method of claim 1 is provided nor is there any motivation cited by *van Asseldonk et al.* to use the *usp45* signal peptide in a method of producing a heterologous peptide, polypeptide, or protein.

Also the Office Action states that “[One] would have been motivated to do so by the well known properties of the *usp45* signal peptide in directing the secretion of a heterologous protein from a lactic acid bacteria, as disclosed by *van Asseldonk et al.*” (Office Action pp. 6). Applicants were unable to locate this disclosure in *van Asseldonk et al.* If Applicants, overlooked this disclosure, they would appreciate the indication of the portion of *van Asseldonk et al.* where it appears.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 15 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Madsen et al.* (WO 98/10079) in view of *Iraelsen et al.*

As noted above, this rejection is improper as it fails to include the independent claim. If the art does not teach or suggest each and every limitation of the independent claim, then it can not meet or suggest each and every limitation of the dependent claims.

While Applicants maintain that claims 15 and 16 were not obvious in view of the aforementioned references, they have cancelled claims 15 and 16 to expedite prosecution, rendering this rejection moot.

Claim Rejections 35 U.S.C. 112

Claims 18 and 19 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

While Applicants maintain that claims 18 and 19 are fully enabled by the specification as filed, these claims have been cancelled to expedite prosecution rendering this rejection moot.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that the application is in condition for allowance and respectfully request a notice of allowance for the pending claims. Should the Examiner determine that any further action is necessary to place this application in condition for allowance, the Examiner is kindly requested and encouraged to telephone Applicants' undersigned representative at the number listed below.

It is believed that no additional fee is due in connection with this filing. However, in the event that any fees are necessary, the Commissioner is hereby authorized to charge our **Deposit Account No. 50-0206**.

Respectfully submitted,
HUNTON & WILLIAMS LLP

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By: _____



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